State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

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March 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products
Docket No. 98N-1265

Dear Sir or Madam:

We are writing to provide the comments of the Wisconsin Pharmacy Examining Board (the "board") to the draft Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products (the "MOU").

The board is the agency responsible in Wisconsin for the licensing and regulation of pharmacists, pharmacies, wholesale distributors, and drug manufacturers located in this state. In that capacity it has had an opportunity to review and discuss the MOU, as well as to receive comments from two pharmacies that will be dramatically effected by the MOU.

The board is concerned with the MOU's definition of "inordinate amounts". It would essentially provide a 20% limit on the prescriptions that may be compounded and distributed interstate by a pharmacy. However, we believe that the term should not be defined in terms of percentages. Rather, it should recognize that specialty compounding, as distinguished from bulk compounding, should be authorized as long the compounding occurs in the context of the physician-patient-pharmacist triad. and appropriate quality controls to assure the prescription is compounded properly.

It should be recognized that specialty compounding pharmacies provide patients and physicians with compounded medications that are not available from manufacturer's, nor from many local pharmacies. The board is aware of and concurs in the FDA's concerns regarding assuring the safety and effectiveness of compounded medications and their impact on patient welfare. However, this service, which is needed on a national basis, does not become more dangerous to the public simply because the compound is shipped interstate. Moreover, the board cannot recall any consumer complaints filed against specialty compounding pharmacies located in this state.

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It appears more likely that the proposed definition of "inordinate amounts" in terms of 20% may only serve to put many specialty compounding pharmacies out business. The definition does not appear to be based upon evidence of substantial patient harm. Rather, patients may be harmed if the specialty compounds that are not available from manufacturers or local pharmacies can no longer be obtained. We believe that that result would be totally inconsistent with the intent of Congress in enacting the Food and Drug Administration Modernization and Accountability Act of 1997 (the "FDAMA"). We believe that compounded substances provided in the context of specific patient-physician-pharmacist relationship, and which comply with the other requirements of the FDAMA, should not be subject to a percentage restriction on interstate distribution.

The board is considering, but has not made any determination on a possible regulatory approach to replace the MOU's 20% definition of "inordinate amounts" of interstate distribution. The percentage criteria contemplated under the MOU may have disastrous effects. We believe it important to understand that specialty compounding pharmacies are a relatively new business that operates on a national scale. It has been suggested that some thought might given toward creating a new registration class for this industry. In any event, careful thought and deliberation is necessary in order to determine the appropriate regulatory approach needed in order to see that specialty compounding pharmacies are not over regulated, or driven out of business completely, while ensuring the health, safety and welfare of patients.

In order to assure the issue is properly discussed and determined, the board strongly requests that the FDA extend its comment period on the proposed MOU to at least August 1, 1999. Having only recently received the draft MOU, we believe many states either are not aware of the implications in the draft or may not be truly aware, in fact, of the issue at all. As you know the National Association of Boards of Pharmacy (the "NABP") is holding its annual convention at the end of May in Albuquerque, New Mexico. We understand that the FDA will be making a presentation on this and other issues to the state pharmacy board representatives at that time. It will be the first time that state representatives will have an opportunity to meet with FDA officials on this matter and to discuss the issues among themselves. In fact, this board may request NABP to permit it to introduce a Resolution on this subject. We believe that a failure to extend the comment period will result in not utilizing the valuable expertise and critical discussion which would be available at the May NABP meeting. The issues are too far reaching in their impact upon appropriate and necessary patient care to not extend the deadline.

The board very much appreciates your consideration of the above concerns.

Sincerely,

Daniel F. Luce, R.Ph.
Chairman, Wisconsin Pharmacy Examining Board

cc: United States Senator Herb Kohl
United States Senator Russell D. Feingold
United States Representative Tammy Baldwin
United States Representative Thomas M. Barrett
United States Representative Mark Green
United States Representative Ronald Kind
United States Representative Gerald D. Kleczka
United States Representative David R. Obey
United States Representative Thomas E. Petri
United States Representative Paul Ryan
United States Representative F. James Sensenbrenner Jr.
National Association of Boards of Pharmacy

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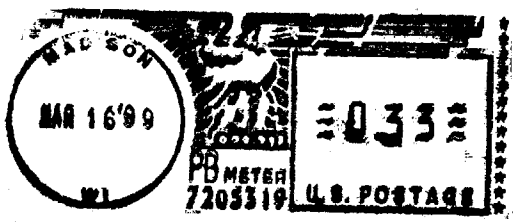

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